K002197

DEC 2 7 2000

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K002197

Applicant Information:
Bernard Graux
Managing Director
Cardionics S.A.
Rue Gabrielle Petit 4/2
B-1080 Brussels.
BELGIUM.

Date Prepared:
November 1, 2000

Proposed Device:
CarTouch ECG Recorder.

Classification:
Cardiovascular
Class II
21 CFR PART : 870.2340

Predicate Device:
Biolog 3000 Electrocardiograph.
The Biolog 3000 is an electrocardiograph that can record the ECG, display the ECG signal on a built-in LCD screen, and download the recorded ECG data to a PC running Cardio View 3000 software or to a Micromedical monitor to display the ECG signal on a personal computer.

Proposed Device Description:
The CarTouch ECG Recorder is an electrocardiograph that allows the user to obtain and to save a standard 12 lead simultaneous electrocardiogram. The CarTouch ECG Recorder can record the full patient's identification, display the 12 leads in real time on the large built-in LCD screen and save 10 seconds of the leads in its flash memory. The CarTouch ECG Recorder can save up to 50 ECGs in its flash memory. The device contains proprietary software to receive ECG data from patient cables, display it on the screen, store the signal into memory and download it to a laser printer.

Statement of Intended Use:
The CarTouch ECG Recorder is a portable electrocardiograph that detects a standard 12 lead electrocardiogram simultaneously from the supplied patient cable. The

CarTouch ECG Recorder uses proprietary software that enables the instrument to record the full patient identification, display the 12 lead waveform in real time on the large built-in LCD screen and save 10 seconds of the leads in its flash memory. The device can save up to 50 ECGs, which can be downloaded to a laser printer. The CarTouch ECG Recorder is designed for use only in hospitals, clinics, and private physician's offices by qualified medical personnel, such as physicians or trained nurses. The CarTouch ECG Recorder is supplied with the User Manual, the patient cable and the printer cable that conforms to the CEI 950 norm. The CarTouch ECG Recorder is compatible with pacemakers and defibrillation shock.

Comparison of Technological Characteristics:
The existing differences between the Predicate device and the CarTouch ECG Recorder involve greater display resolution , 12 lead real-time display, and a 50 ECG result memory for the proposed device.
The differences do not affect safety and effectiveness of the device.

Testing:
Nonclinical performance testing was performed according to the EC11 standard (ANSI/AAMIEC11–1991 *Diagnostic electrocardiographic devices*). This electrical test has been conducted by SGS United Kingdom Limited, 217-221 London Road, Camberley, Surrey, United Kingdom, GU15 3 EY.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 2 7 2000

Cardionics, Inc.
c/o Mr. Jeff Morgan
JWM Associates
13273 Dana Lane East
Puyallup, WA 98373

Re: K002197
Trade Name: CarTouch Electrocardiograph Recorder
Regulatory Class: II (two)
Product Code: DPS
Dated: Undated
Received: November 6, 2000

Dear Mr. Morgan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

per

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number: K002197

Device Name: CarTouch ECG Recorder

Indication for Use:

The CarTouch ECG Recorder is a portable electrocardiograph that detects a standard 12 lead electrocardiogram simultaneously from the supplied patient cable. The CarTouch ECG Recorder uses proprietary software that enables the instrument to record the full patient identification, display the 12 lead waveform in real time on the large built-in LCD screen and save 10 seconds of the leads in its flash memory. The device can save up to 50 ECGs, which can be downloaded to a laser printer. The CarTouch ECG Recorder is designed for use only in hospitals, clinics, and private physician's offices by qualified medical personnel, such as physicians or trained nurses. The CarTouch ECG Recorder is supplied with the User Manual, the patient cable and the printer cable that conforms to the CEI 950 norm. The CarTouch ECG Recorder is compatible with pacemakers and defibrillation shock

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Concurence of CDRH, Office of Device Evaulation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002197

Prescription Use Only

(Optional Format 3-10-98)